COMPASS IRB
GUIDING YOU TO SUCCESS

5416 East Baseline Road, Suite 120, Mesa, AZ 85206
Phone: (480) 832-7373 or (877) 660-1IRB
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www.compassirb.com

Unanticipated Problems Reporting Form

Instructions: Only items meeting the definition of an unanticipated problem are required to be reported to the IRB. All unanticipated problems should be reported to Compass IRB within 10 working days of discovery (except when event is a death in which case please report within 5 working days of discovery). Please read and complete all sections carefully and attach corresponding report. Any missing information may result in a delay in the review.

Sponsor:	**Protocol #:**
Principal Investigator's Name:	
Compass IRB #:	

Definitions

Unanticipated problem - Any event or information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm. The harm does not have to be a direct harm to be reportable. The harm, as assessed by the PI or monitoring agent, has presented increased risk (e.g., losing a laptop with subject data). Additionally, the harm doesn't have to be the harm to subjects it could involve risk to others (researchers, technicians, bystanders, the public, etc.). *Note: non-medical events (e.g., breach of confidentiality, emotional breakdown, loss of insurance, etc.). if unanticipated - would also be reportable to the IRB.*

Unanticipated/Unexpected- An event is unanticipated or unexpected when its specificity or severity is not consistent with the current investigator brochure, protocol, consent form, package insert or label; or is unanticipated in its frequency, severity, or specificity.

Related – An event is related to a research procedures if it was more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.

Adverse Event – Is any physical, psychological or social harm to subjects during the course of research.

Event Type (Check box that applies.)

- ☐ Adverse Event which in the opinion of the principal investigator is both **unexpected and related**.
  ***Please attach full SAE and/or UADE Report as submitted to Sponsor for review.*
- ☐ An unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk.
- ☐ Information that indicates a change to the risks or potential benefits of the research.
  For example: a.) an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB, b.) a paper is published from another study that shows that the risks or potential benefits have changed.
- ☐ A breach of confidentiality
- ☐ Incarceration of a participant in a protocol not approved to enroll prisoners
- ☐ Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant
- ☐ Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team
- ☐ Event that requires prompt reporting to the Sponsor
- ☐ Sponsor imposed suspension for risk
- ☐ Event that was **not** related or unexpected and meets no other reporting criteria noted above. (This does not have to be reported to the IRB, but will be accepted and sent to file.)

Event Identification	
Event date:	Subject Initials or Case # (if applicable):
Was the event study-related? ☐ Yes ☐ No	
Select one: ☐ Initial report to IRB ☐ Follow-up* *If follow-up, please proceed to ***Document Attachments*** section	

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Event Details
Briefly describe the circumstances of this event:
Classify the event (e.g. pregnancy, death, adverse event, life-threatening, prolonged hospitalization, etc.)
How long did the event last?
Do you plan to notify ***currently*** enrolled subjects of this event? ☐ Yes* ☐ No Do you plan to notify ***completed*** subjects of this event? ☐ Yes* ☐ No *If yes, describe method of notification:
Do you expect this event to occur again? ☐ Yes ☐ No
Is the event effectively described in the consent form and protocol? ☐ Yes ☐ No
Should the consent form be modified as a result of this event? ☐ Yes* ☐ No *If yes, please submit your recommended changes.

Subject Details
Subject's age: Gender: ☐ Male ☐ Female
Did this event involve a healthy volunteer? ☐ Yes ☐ No
Subject Status: ☐ Pre-screening ☐ Follow-up ☐ Dosed/Randomized ☐ Completed

Protocol/Research Details
Enrollment status at your site (check one): ☐ Open to enrollment ☐ Closed to enrollment (select one): ☐ Active subjects and/or subjects in follow-up ☐ No active subjects ☐ Study on hold ☐ Study completed – No further study-related activity at your site
Indicate where this research is taking place: ☐ Multi-center study, and the event occurred here ☐ Multi-center study, but the event occurred off-site ☐ Single-site study, this study is only being conducted at my site
My protocol involves: ☐ Investigational Drug ☐ Investigational Device ☐ Other (describe):

Document Attachments
Does this event prompt a change to the Consent Document(s)? ☐ Yes* ☐ No *If yes, attach a redlined copy of the document.
Does this event prompt a change to the protocol? ☐ Yes* ☐ No *If yes, attach a redlined protocol revision.
Does this event prompt a change to the Investigator's Brochure/Package Insert/User's Manual? ☐ Yes* ☐ No **If yes, attached a redlined revision to the document.

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Additional Information	
Is there any additional information you need to share with Compass IRB?	☐ Yes* ☐ No
*If yes, please use this space to share with us?	

I hereby certify that I have fully disclosed all information pertaining to this event and that the above-referenced information is accurate.

Signature of Submitting Party:

Name _____ Title _____

Signature _____ Date _____

COMPASS IRB INTERNAL USE ONLY: CIRB Staff ID: _____

Is this report appropriate for review? ☐ **Yes** ☐ **No**

If "No," please list reason that report is inappropriate for review (e.g. does not meet definition of unanticipated problem, incomplete report):

Decision of Reviewer:

Is this event an unanticipated problem that involves risk to participants or others? ☐ Yes ☐ No

Is there information in this report that involves an allegation of non-compliance? ☐ Yes** ☐ No

If yes, must request a site audit and/or send to Full Board.

☐ **No further action necessary**
☐ **Request additional information***
☐ **Call Site / Sponsor for discussion***
☐ **Request Audit***
☐ **Send to Full Board**

Comments/Notes (as needed):

Signature of Board Reviewer _____ Date _____

* If checked, please attach all follow-up documentation to this report and resubmit to Board Reviewer.

Please mail, email to submissions@compassirb.com, or fax this form to (480) 832-7376.

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